K062691

510(k) Summary

APR 15 2008

Comporus™

Submitter's name:	Takiron Co., Ltd.
Submitter's address:	3-13 Azuchi-machi 2-chome, Chuo-ku, Osaka 541-0052, Japan
Contact Person:	Kenshi Okazaki Shikinami Laboratory, Medical Division 405 Nagano, Yasutomi-cho, Himeji, Hyogo, 671-2421, Japan Phone: +81 790 66 2411 Facsimile: +81 790 66 3717 ken-oka@takiron.co.jp
Date prepared:	August 30, 2006
Trade or proprietary name:	Comporus™
Common name:	Resorbable Synthetic Bone Void Filler
Classification name:	Resorbable calcium salt bone void filler (Product Code MQV) is a Class II device, per 21 CFR 888.3045.

Establishment Registration Number:
Takiron Co., Ltd. has not yet obtained an Establishment Registration Number.

Legally Marketed Predicate Devices:
INTERPORE International; Pro Osteon® 500R Resorbable Bone Void Filler (K980817)
Orthovita, Inc.; Vitoss® Scaffold Synthetic Cancellous Bone Void Filler (K032409)
OsteoBiologics, Inc.; PolyGraft™ BGS; Bone Graft Substitute (K030288)
Berkeley Advanced Biomaterials, INC.; Bi-Ostetic™ (K023703)

Intended Use:

Comporus™ is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Comporus™ is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with new bone during the healing process.

Device Description:

Comporus™ is an osteoconductive biodegradable scaffold used as bone void filler. It is manufactured from a mixture of poly-D/L-lactide and hydroxyapatite and provided in granule, block and cylinder forms. They may be pressed into the void or into the surgical site by hand. Comporus™ was shown to be biocompatible. Used properly, the implant is resorbed and replaced with natural bone during the healing process. Comporus™ is sterile and intended for single use only. It is radiopaque and has the ability to be modified intraoperatively by trimming or thermal transformation to be adjusted to the shape of a defect.

Summary of Technology:

Comporus™ has similar compressive strength to the predicate devices and cancellous bone. Comporus™ has the similar technological characteristics (i.e., design and material) when compared to the predicate devices.

Substantial equivalence:

The Comporus™ and the predicate devices have the same intended use and principles of operation and very similar technological characteristics. Furthermore, the minor technological differences between the Comporus™ and the predicate devices do not raise any new issues of safety or effectiveness. Preclinical testing was performed and demonstrates that the device is substantially equivalent to the predicate. Therefore, the Comporus™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Takiron Co., Ltd.
% Medical Division
Dr. Kenshi Okazaki
405 Nagano, Yasutomi-Cho
Himeji
Japan 671-2421

APR 15 2008

Re: K062691
Trade/Device Name: Comporus™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 18, 2008
Received: January 22, 2008

Dear Dr. Okazaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Takiron Co., Ltd.
510(k) Number (if known): K062691
Device Name: Comporus™

Indications For Use:

Comporus™ is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Comporus™ is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with new bone during the healing process.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062691